

July 5, 1999

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

7842 '99 JUL 12 A10:35

Docket No. 99D-1541 (64 FR 30041)

I am using this opportunity to voice my opinion that tracking the effects of all drugs or biologics taken before or during pregnancy is extremely necessary for the health of future generations. However, we should not only track the use of drugs and biologics taken by the mother, but *it is imperative that we begin testing and tracking the long term effects of drugs and biologics on the father's reproductive health and risk of birth defects in children.* For example, if the hair growth treatment Propecia is so toxic that pregnant women are warned not to *touch* it, what effect is it having on those men's sperm? What is the long term effect on the future children of our military men and women being forced to take the anthrax vaccine? No one knows - but children may pay a high price for our ignorance.


Labels for all drugs and biologics should err on the side of conservatism. Unless studies indicate otherwise, their labels should include warning language such as:

"The long term risk of this drug/biologic with respect to adult reproductive health and occurrence of birth defects has not been studied."

Obviously, if studies have been conducted the labels should reveal the results of the study as well as identify the entity conducting the study and its relationship to the manufacturer.

If the true long term side effects of all pharmaceuticals were known, I think we would see greater acceptance of more natural healing and preventive treatments by the "mainstream" medical and regulatory communities. Natural therapies are extremely effective, have virtually no side effects (unlike pharmaceuticals), and are far less costly to consumers.

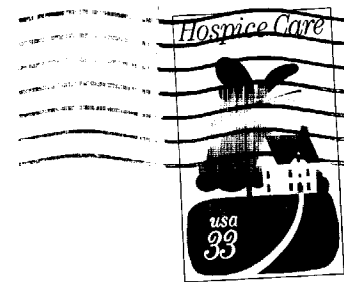
Sincerely,


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99D-1541

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